

SPL Process ER/DL Meeting Meeting Minutes Mar 25, 2015

Chair of today's meeting: Mary Beth Wilusz

Teleconference information:

USA Toll-Free 866-213-2145

USA Paid/International: 609-454-9913

Access code: 273 8216

Teleconference information: How to mute/unmute

#6: Mute

*6: Unmute

Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

Agenda:

1. Update: SPL for Lot Distribution Reports

- Vendors are getting ready. They need to know what is required. It looks like additional information is required. Would like to talk about this at the next team meeting. How would the conversion business get the information that they need to create the SPL – therefore the SPL needs to be in the data provided.
- See pdf page 130, 129 in the SPL implementation guide. – for a plain English description of what information is required. Some information is coming from the drug listing. But they need to be able to link the lot distribution data with the drug listing.

Update:

- Testing is happening with CBER – have contacted companies to submit files. Too early for feedback
- Someone in our group offered to show others an example of the file. We will discuss logistics and plan this at a future meeting.

2. Question: FDA contacted GSK to revise their NDC numbers to change their NDC codes based on the guidance below. Has anyone been asked to revise existing NDCs to avoid sequential numbering per Draft Guidance for Industry: Safety considerations for container labels and carton labeling design to minimize medication errors. April 2013.

<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm349009.pdf>

- Has anyone received this request?
 - No one on the phone call has received this request.
 - GSK will get back to us on their response and how they work this out.

3. Question on timing for de-listing – are people still using last lot expiry as marketing end date?

- Yes. Many companies are using last lot expiry for a market end date.
- Process:
 - Step 1: Put in the market end date
 - Step 2: Remove the product from the SPL at a convenient time. It is helpful to leave in for at least a year, since CMS may reimburse for up to a year after last lot expiry.
- The NSDE is a cumulative file. Expired products remain in the NSDE directory.
- Are both CDER and CBER accepting data down to the pack level.
 - Pack level only works for CDER products.
 - Validation rule 3.1.8.14, page 49 or 50 of the IG.

4. Question about UNII for simethicone vs dimethicone. simethicone is official nomenclature but dimethicone is in UNII list – is this what other companies are doing and are there any concerns about this?

- This was discussed several years ago. FDA said that the correct way to specify the compound is as two substances: dimethicone and silicon dioxide
- An open question is how to specify the dimethicone viscosity, there are several viscosities for the substance.
- For previous discussions on the SPL Wiki Group forum (<http://spl-work-group.wikispaces.com/>) search for simethicone.

5. Question: During the last meeting there was a discussion about drug listing exports.

- Does anyone have the specific regulatory citation that states exports need to be drug listed?
- Are APIs covered under 207.20?
- Is there another document regulatory citation?
- Does this include IFEs? (Import for Export)

This was discussed at the last meeting. Here are the minutes from the last meeting-
Part A: A site in the U.S. will only be manufacturing for the rest of the world, not the U.S. market. Does it need to have an establishment registration? If yes, what regulation says this?

FDA Compliance Officer Response: The site does not have to be registered under these circumstances

Part B: The above site is being provided API from outside the U.S. Can the API manufacturer be inspected by the FDA, even though it will not be used in the manufacture of U.S. marketed product? Which regulation says this?

FDA Compliance Officer Response: The API manufacturer can be inspected by FDA if they make the API under consideration in this case for another domestic firm producing the dosage form.

Also, the foreign API supplier could be making different APIs used for domestically produced dosage form products. This could result in inspection.

These are the only two circumstances which I can think of meriting inspection of the API firm.

Comment to Ben: Please contact EDRLS@fda.hhs.gov directly with these questions. I have heard a variety of opinions regarding the questions and provide us with a follow-up.

Who Must Register

The owner or operator of an establishment entering into the manufacture, preparation, propagation, compounding, or processing (which includes, among other things, repackaging and relabeling) of a drug or drugs¹⁴ and not exempt under section 510(g) of the Act or subpart B of 21 CFR part 207, must register the establishment with FDA within 5 days after beginning the operation (21 CFR 207.21(a) and 21 CFR 207.3(a)(8)).

Sec. 207.40 Establishment registration and drug listing requirements for foreign establishments.

(a) Foreign drug establishments whose drugs are imported or offered for import into the United States shall comply with the establishment registration and drug listing requirements in subpart C of this part, unless exempt under subpart B of this part or unless the drugs enter a foreign trade zone and are re-exported from that foreign trade zone without having entered U. S. commerce.

No drug may be imported into or offered for import into the United States unless it is listed as required in subpart c of this part and manufactured, prepared, propagated at a registered foreign drug establishment

IMPORT FOR EXPORT PROVISIONS FOR PRODUCTS MANUFACTURED IN FOREIGN TRADE ZONES

Foreign Trade Zones are federally sanctioned sites that, only for tariff purposes, are considered outside of the "Customs territory" of the United States. Nevertheless, products stored or manufactured in a Foreign Trade Zone are within the territory of the United States for the purposes of the Act and are expected to meet the same requirements as other products regulated by FDA [see Compliance Policy Guides 110.600 "FDA Authority Over Products of Foreign Origin Located in Foreign Trade Zones, Bonded Warehouses, or on Bonded Carriers", and 110.200 "Export of FDA Regulated Products from U.S. Foreign Trade Zones"]]. These include the requirements of section 801(d)(3) and section 801(d)(4).

This sounds like it might be an import for export – and might be covered by those requirements.

<http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179481.htm>

as well as section 801 of FD&C?

<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/t/FDCAActChapterVIIIImportsandExports/ucm107032.htm>

- There is a category "for Export Only", for drug listing product for export only.
- Actually a final product...
- Used a file type of Human Prescription Drug without highlights – therefore needed to add a section of text – used temperature range.
- Suggestion – manufactured exclusively for private label distributor
- See NDC on Daily Med: 0173707700

Ben Harpster to follow-up and report back. Here is GSK product for export only on Daily Med

<http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3fdc827c-182f-435c-a576-ba90d452ec7e>

6. FYI: enclosure - federal register notice – Agency Information Collection Activities: Proposed Collection; Comment Request; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution (comments due 22-May-2015)

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[Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution](#)

FR Doc No: 2015- 06497

Docket No. FDA-2011-N-0742

7. Is anyone using the esubmitter to submit information for the GDUFA self identification?
- o Kathy Lins had a new computer and lost her old files.
 - o She may have to reenter the information. You can have a different set id each year.

Tricia Pasek confirmed this:

The use of the same Set-ID from a previous Fiscal Year is allowed but NOT required for a new submission in the subsequent Fiscal Year.

Submitters can use the same SPL file they used previously if no self-identification information has changed, with the following notes:

- a. same set ID (from a previous Fiscal year i.e.2014),
- b. a version number higher than previous version and
- c. a new document ID.

Please Note that once an initial Set-ID is selected for a Fiscal Year (May 1st through April 31st) it should be used in subsequent SPL submission updates for the entirety of that Fiscal Year. Submitters can only change SetID's between submission years.

Thank you for contacting CDERFacility@fda.hhs.gov. If you have additional inquiries feel free to contact us via email for further assistance. Thank you.

Very Respectfully,

Tier 1 Support
Self-Identification & ACA Helpdesk Team
CDERFacility@fda.hhs.gov

8. Wholesalers and 3rd party distributors must report their licenses by March 31, 2015 using SPL. FDA is maintaining the Mar 31, 2015 date.

Main page is

<http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm423749.htm>

Page has link to guidance
